

REMARKS

Claims 1-119 are pending. In the instant amendments, claims 25, 29-43, 45-48, 63-76, 78-102, 110-115, 118 and 119 have been canceled without prejudice as explained below. Claims 1-6, 12, 44, 49-53, 56, 77 and 117 have been amended. Upon entry of the amendments, claim 1-24, 26-28, 44, 49-62, 77, 103-109, 116 and 117 will be pending and under consideration.

I. AMENDMENTS TO THE SPECIFICATION

The specification has been amended on pages 7 and 32 to correct the abbreviation for the heavy chain variable region of the 16H9 antibody as "16H9H."

The specification has been amended on pages 8 and 33 to correct a typographical error. The sequence listing identifier for the light chain polypeptide variable region for the 16H9 antibody has been changed to "SEQ ID NO:56."

These amendments to the specification are supported by the specification as originally filed. As no new matter has been added with these amendment, entry thereof is respectfully requested.

II. AMENDMENTS TO THE CLAIMS

Claims 25, 32, 38, 63-76, 110-112, 118 and 119, as well as claims 29-31, 33-37, 39-43, 45-48, 78-102 and 113-115, which are directed to nonelected subject matter, have been canceled without prejudice to Applicants' rights to pursue the canceled subject matter in one or more other applications.

Claims 1 and 77 have been amended to recite "wherein the isolated antibody, or the antigen-binding antibody fragment, binds a repeat region present within SEQ ID NO:1." Support for this amendment is found in the specification, for example, page 27, para. 0117.

Claims 2-6 and 12 have been amended to recite "SEQ ID NO:1." Claim 44 has been amended in its dependency. Claims 49-53 have been amended to recite "SEQ ID NO:1" and to remove a trademark or tradename. Claim 56 has been amended to define the abbreviation "ADCC," as supported by the specification at page 3, para. 0014. Claim 117 has been amended to recite an "isolated" antibody or antigen-binding antibody fragment.

The instant amendments to the claims are fully supported by the specification and claims as originally filed, and do not add new matter. Entry of the amendments to the claims is respectfully requested.

No claim amendment fee is believed to be due since the number of independent claims and total claims have been reduced with these amendments.

III. OBJECTION TO THE SPECIFICATION

The Patent Office objects to the abbreviation for the heavy chain variable region of the 16H9 antibody provided on pages 7 and 32 of the specification. The abbreviation has been corrected in the instant amendments to the specification. Withdrawal of the objection to pages 7 and 32 of the specification is respectfully requested.

The Patent Office objects to the sequence identification number associated with 16H9L on pages 8 and 33, noting that SEQ ID NO:33 should be associated with antibody 776.1. The specification has been amended to identify SEQ ID NO:56 as the sequence identification number for 16H9L. Withdrawal of the objection to pages 8 and 33 of the specification is respectfully requested.

IV. OBJECTION TO THE CLAIMS

The Patent Office objects to claims 2-6, 12, 49-53 and 119 because the claims recite "Figure 1." Claim 119 has been canceled and the remaining claims have been amended to recite "SEQ ID NO:1" as suggested by the Examiner. Withdrawal of the objection to claims 2-6, 12, 49-53 and 119 is respectfully requested.

The Patent Office objects to claims 56-60 because the claims recite the abbreviation ADCC without first defining the abbreviation in the claims. Claim 56 has been amended to define the abbreviation the first time it is used in the claims. Withdrawal of the objection to claims 56-60 is respectfully requested.

V. CLAIM REJECTION UNDER 35 U.S.C. § 101

Claim 117 stands rejected under 35 U.S.C. § 101 since the claimed antibody is encompasses non-statutory subject matter. Claim 117 has been amended as suggested by the Examiner. The withdrawal of the rejection of Claim 117 under 35 U.S.C. § 101 is respectfully requested.

VI. CLAIM REJECTION UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

Claims 1-25, 49-76, 103-106 and 110-112 stand rejected under 35 U.S.C. § 112, second paragraph, for indefiniteness. Claims 49-53 stand rejected under 35 U.S.C. § 112, second paragraph, for use of a trademark or tradename in the claims.

A. Claims 1-25, 49-76, 103-106 and 110-112

Claims 1-25, 49-76, 103-106 and 110-112 stand rejected under 35 U.S.C. § 112, second paragraph, for indefiniteness regarding the phrases “cell-associated CA 125/O772P” or “shed CA 125/O772P.” The rejection of claims 25, 63-76 and 110-112 is moot since these claims have been canceled.

The specification states that a “CA 125/O772P *cell-associated polypeptide species* is present within amino acid residues 1 to 708 of SEQ ID NO:1.” *See* page 18, para. 0063 (emphasis added). Within this portion of SEQ ID NO:1 are three repeat domains located in amino acids 14-452 of SEQ ID NO:1. *See* page 22, para. 84. Independent claim 1 has been amended, as suggested by the Examiner, to recite SEQ ID NO:1 when referring to the CA 125/O772P polypeptide. Claims 2-25, 49-62 and 103-106 depend from claim 1 and include elements of the independent claim 1 from which they depend, including, for example, the SEQ ID number recited in the independent claim.

Accordingly, it is respectfully requested that the Patent Office withdraw the rejection of claims 1-25, 49-76, 103-106 and 110-112 under 35 U.S.C. § 112, second paragraph.

B. Claims 49-53

Claims 49-53 stand rejected under 35 U.S.C. § 112, second paragraph, for reciting the trademark/tradename “BIAcore Affinity Assay.” The rejection is obviated in light of the amendments to claims 49-53. Applicants respectfully request that the rejection of claims 49-53 under 35 U.S.C. § 112, second paragraph, be withdrawn.

VII. REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH, FOR LACK OF WRITTEN DESCRIPTION

Claims 26-28, 107-109 and 116-118 stand rejected under 35 U.S.C. § 112, first paragraph, for lack of written description. Claims 1-25, 49-76, 103-106 and 110-112 stand rejected under 35 U.S.C. § 112, first paragraph, for lack of written description.

A. Claims 26-28, 107-109 and 116-118

Claims 26-28, 107-109 and 116-118 stand rejected under 35 U.S.C. § 112, first paragraph, for lack of written description. The Patent Office contends that an affidavit or declaration by applicant, or a statement by an attorney of record is required to assure that the deposited material recited in claims 26-28, 107-109 and 116-118 will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, and that the deposit will be replaced if viable samples cannot be dispensed by the depository. Statements regarding the deposits of biological materials with the American Type Culture

Collection (ATCC), including the ATCC accession numbers and provisions under which the deposits were made, are already in the specification as originally filed. Nevertheless, enclosed is a Statement Regarding the Permanence and Availability of Deposited Hybridomas (“Statement”) by Applicants’ Attorneys, which attests to the deposit of the monoclonal-secreting hybridomas according to the provisions of the Budapest Treaty, in compliance with the criteria set forth by 37 C.F.R. §§ 1.801-1.809. Entry of the Statement into the record is respectfully requested.

Accordingly, Applicants respectfully request the withdrawal of the rejection of claims 26-28, 107-109 and 116-118 stand rejected under 35 U.S.C. § 112, first paragraph.

B. Claims 1-25, 49-76, 103-106 and 110-112

Claims 1-25, 49-76, 103-106 and 110-112 stand rejected under 35 U.S.C. § 112, first paragraph, for lack of written description. The rejection of claims 25, 63-76 and 110-112 is moot since these claims have been canceled. Applicants respectfully traverse the rejection of amended claims 1-24, 49-62 and 103-106.

To meet the written description requirement the applicant must “convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the ‘written description’ inquiry, whatever is now claimed.” *Vas-Cath Inc. v. Mahurkar*, 19 U.S.P.Q.2d 1111, 1117 (Fed. Cir. 1991).

The instant specification conveyed with reasonable clarity to those skilled in the art, as of the earliest claimed priority date, that Applicants were in possession of the subject matter of amended claims 1-24, 49-62 and 103-106. For example, amended independent claim 1 recites an antibody that, *inter alia*, binds a repeat region present within SEQ ID NO:1, and the specification teaches that this repeat region is preferentially present in cell-associated CA 125/O772P polypeptide. *See, e.g.*, page 2, para. 0010, page 18, para. 0063, and page 22, para. 0084. Hence, the specification describes the genus of antibodies that preferentially bind cell-associated CA 125/O772P polypeptide recited in claim 1 and in the claims that depend from claim 1.

For the foregoing reasons, Applicants respectfully request that the rejection of claims 1-25, 49-76, 103-106 and 110-112 under 35 U.S.C. § 112, first paragraph, be withdrawn.

VIII. REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH, FOR LACK OF ENABLEMENT

Claims 63-76, 110-112 and 118 stand rejected under 35 U.S.C. § 112, first paragraph, as being non-enabled. Claims 25, 32 and 38 stand rejected under 35 U.S.C. § 112, first paragraph, as being non-enabled.

A. Claims 63-76, 110-112 and 118

Claims 63-76, 110-112 and 118 stand rejected under 35 U.S.C. § 112, first paragraph, as being non-enabled. Although Applicants in no way acquiesce to the propriety of the rejection, nonetheless to expedite prosecution, claims 63-76, 110-112 and 118 have been canceled in the instant amendments to the claims. Withdrawal of the rejection of claims 63-76, 110-112 and 118 under 35 U.S.C. § 112, first paragraph, is respectfully requested

B. Claims 25, 32 and 38

Claims 25, 32 and 38 stand rejected under 35 U.S.C. § 112, first paragraph, as being non-enabled. Without acquiescing to the propriety of the rejection, and to expedite prosecution, Applicants have canceled claims 25, 32 and 38 leaving the rejection of these claims moot. Withdrawal of the rejection of claims 25, 32 and 38 under 35 U.S.C. § 112, first paragraph, is respectfully requested.

IX. REJECTION UNDER 35 U.S.C. § 102(b)

Claim 119 stands rejected under 35 U.S.C. § 102(b) as being anticipated by Yin and Lloyd (2001) *J. Biol. Chem.* 276, 27371-27375. Although Applicants in no way acquiesce to the propriety of the rejection, nonetheless to expedite prosecution, claim 119 has been canceled in the instant amendments to the claims. Withdrawal of the rejection of claim 119 under 35 U.S.C. § 102(b) as being anticipated by Yin and Lloyd is respectfully requested.

Claim 119 stands rejected under 35 U.S.C. § 102(b) as being anticipated by Mitcham *et al.*, WO 00/36107, published June 22, 2000. Although Applicants in no way acquiesce to the propriety of the rejection, nonetheless to expedite prosecution, claim 119 has been canceled in the instant amendments to the claims. Withdrawal of the rejection of claim 119 under 35 U.S.C. § 102(b) as being anticipated by WO 00/36107 is respectfully requested.

CONCLUSION


Applicants thank the Examiner for her suggestions made in the Office Action dated May 3, 2006.

In light of the above amendments and remarks, Applicants respectfully request that the Patent Office reconsider this application with a view towards allowance.

No fee, other than that for an extension of time, is believed to be due with this paper. However, the Commissioner is hereby authorized to charge any required fee to Jones Day deposit account No. 50-3013 (referencing no. 305158-999212). A copy of this sheet is enclosed.

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Respectfully submitted,

 54,398

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